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IMPORTANT NOTICE: Zinecard® Supply Situation

Dear Health Care Provider,

This letter is to update you on the current supply situation for Zinecard (dexrazoxane for Injection). The reason for the shortage of Zinecard was that the diluent, 0.167 Molar Sodium Lactate USP that was co-packaged with Zinecard, did not meet the particulate matter acceptance criteria according to USP. Although Pfizer is working on a long-term solution by investigating the root cause of this diluent quality issue, a short-term solution is also necessary to ensure that patients have access to this important component of their treatment.

Previously, Pfizer removed the Sodium Lactate USP from the package and re-introduced Zinecard as a single unit of sale. The single unit of sale Zinecard was distributed with a Dear Health Care Provider Letter which contained the instructions for reconstitution with other sources of 0.167 Molar Sodium Lactate Injection USP.

For all new and as yet unfilled orders for Zinecard, Pfizer will ship both the product and a bag of the diluent (0.167 Molar Sodium Lactate Injection USP) meeting all USP specifications including the particulate matter limits (or acceptance criteria). For previously distributed Zinecard, if there is no appropriate diluent available, Pfizer will ship a bag of the 0.167 Molar Sodium Lactate Injection USP upon request. Each single unit vial of Zinecard will now be distributed with a copy of the Dear Health Care Provider Letter which contains the instructions for reconstitution with the bag of 0.167 Molar Sodium Lactate Injection USP. Consequently, orders for more than one vial of Zinecard will contain an equivalent number of diluent bags and copies of the letter. **To order Zinecard, please contact your wholesaler to arrange a drop shipment from Pfizer. If you have any questions regarding your order, please contact Pfizer's Customer Service at (800) 533-4535.**

Product Information:

Zinecard is a sterile, pyrogen-free lyophilizate intended for intravenous administration. It is a cardioprotective agent for use in conjunction with doxorubicin. Zinecard is available in 250 mg and 500 mg single use vials.

- Each 250 mg vial contains dexrazoxane hydrochloride equivalent to 250 mg dexrazoxane. Hydrochloric Acid, NF is added for pH adjustment.
- Each 500 mg vial contains dexrazoxane hydrochloride equivalent to 500 mg dexrazoxane. Hydrochloric Acid, NF is added for pH adjustment.

Instructions for Reconstitution of Zinecard

At this time, only 0.167 Molar Sodium Lactate Injection USP has been studied for compatibility and stability with Zinecard. Therefore Zinecard should only be reconstituted with 0.167 Molar Sodium Lactate Injection USP. No other diluent should be used to reconstitute Zinecard. Any unused Sodium Lactate Injection should be discarded.

The amount of diluent used for reconstitution will need to be appropriately proportioned according to the package insert (PI) for Zinecard, as follows:

- **A 250 mg single use vial of dexrazoxane should be reconstituted with 25 mL of 0.167 Molar Sodium Lactate Injection, USP. Once reconstituted the resultant solution contains 10 mg dexrazoxane per mL.**

- **A 500 mg single use vial of dexrazoxane should be reconstituted with 50 mL of 0.167 Molar Sodium Lactate Injection, USP. Once reconstituted the resultant solution contains 10 mg dexrazoxane per mL.**

As long as the reconstitution instructions for Zinecard are followed as described within this letter, there are no anticipated changes to the safety and efficacy of Zinecard to patients.

The reconstituted Zinecard solution may be diluted with either 0.9% Sodium Chloride Injection, USP or 5.0% Dextrose Injection, USP to a concentration range of 1.3 to 5.0 mg/mL in intravenous infusion bags. The resultant solutions are stable for 6 hours when stored at controlled room temperature, 15° to 30°C (59° to 86°F) or under refrigeration, 2° to 8°C (36° to 46°F). DISCARD UNUSED SOLUTIONS.

NDC Codes

The NDC codes for the single-unit vials packaged **without** diluent have been changed. However, the package insert included with the single-unit vials has not been updated. Hence, the NDC codes in the Package insert designated for the vials have not been changed. The following table shows the NDC codes, as reflected on the product labels and in the Package Insert.

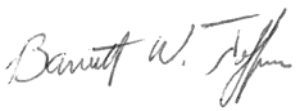
Previous and Current NDC#s for Zinecard Vials

	Previous Zinecard NDC#*	Current Zinecard NDC#†
Zinecard 250 mg vial	0013-8715-62	0013-8717-62
Zinecard 500 mg vial	0013-8725-89	0013-8727-89

*Reflected in current Zinecard Package Insert
†Reflected on current single-unit vials

Please direct any questions related to the content of this Dear Health Care Provider Letter to Pfizer Medical Information at 1-800-438-1985. For questions related to the distribution of or to order Zinecard, please contact Pfizer Customer Service at (800) 533-4535.

Sincerely,



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